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By: **Delegates Cole and McHale**  
Introduced and read first time: February 16, 2001  
Assigned to: Rules and Executive Nominations

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A BILL ENTITLED

1 AN ACT concerning

2 **Pharmacy Errors**

3 FOR the purpose of requiring a pharmacy for which a pharmacy permit has been  
4 issued to immediately report, after discovery, to the consumer, the consumer's  
5 prescribing health care provider, and the Board of Pharmacy, any error the  
6 pharmacy makes in compounding, dispensing, or labeling a prescription;  
7 providing sanctions for a failure to make a report; requiring the Board to adopt  
8 certain regulations by a certain date; and requiring the Board to make a certain  
9 annual report to certain committees of the General Assembly.

10 BY repealing and reenacting, with amendments,  
11 Article - Health Occupations  
12 Section 12-313(b) and 12-403(b)  
13 Annotated Code of Maryland  
14 (2000 Replacement Volume)

15 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF  
16 MARYLAND, That the Laws of Maryland read as follows:

17 **Article - Health Occupations**

18 12-313.

19 (b) Subject to the hearing provisions of § 12-315 of this subtitle, the Board, on  
20 the affirmative vote of a majority of its members then serving, may deny a license to  
21 any applicant, reprimand any licensee, place any licensee on probation, or suspend or  
22 revoke a license if the applicant or licensee:

23 (1) Fraudulently or deceptively obtains or attempts to obtain a license  
24 for the applicant or licensee or for another;

25 (2) Fraudulently or deceptively uses a license;

26 (3) Aids an unauthorized individual to practice pharmacy or to represent  
27 that the individual is a pharmacist;

- 1           (4)     Provides professional services while:
- 2                   (i)     Under the influence of alcohol; or
- 3                   (ii)    Using any narcotic or controlled dangerous substance, as  
4 defined in Article 27 of the Code, or other drug that is in excess of therapeutic  
5 amounts or without valid medical indication;
- 6           (5)     Submits a false statement to collect a fee;
- 7           (6)     Willfully makes or files a false report or record as part of practicing  
8 pharmacy;
- 9           (7)     Willfully fails to file, MAKE, or record any report that is required by  
10 law, INCLUDING THE REPORT TO A CONSUMER, PRESCRIBING HEALTH CARE  
11 PROVIDER, AND THE BOARD REQUIRED UNDER § 12-403(B)(13)(II) OF THIS TITLE;
- 12          (8)     Willfully impedes or obstructs the filing or recording of any report  
13 that is required by law;
- 14          (9)     Willfully induces another to fail to file or record any report that is  
15 required by law;
- 16          (10)    Provides or causes to be provided to any authorized prescriber  
17 prescription forms that bear the name, address, or other means of identification of a  
18 pharmacist or pharmacy;
- 19          (11)    Provides remuneration to an authorized prescriber for referring an  
20 individual to a pharmacist or pharmacy for a product or service to be provided by that  
21 pharmacist or pharmacy;
- 22          (12)    Agrees with an authorized prescriber to prepare or dispense a secret  
23 formula prescription;
- 24          (13)    Except as to an association that has remained in continuous  
25 existence since July 1, 1963, associates as a partner, coowner, or employee of a  
26 pharmacy that is owned wholly or substantially by an authorized prescriber or group  
27 of authorized prescribers;
- 28          (14)    Dispenses any drug, device, or diagnostic for which a prescription is  
29 required without a written, oral, or electronically transmitted prescription from an  
30 authorized prescriber;
- 31          (15)    Except as provided in § 12-506 of this title, unless an authorized  
32 prescriber authorizes the refill, refills a prescription for any drug, device, or  
33 diagnostic for which a prescription is required;
- 34          (16)    Violates any provision of § 12-505 of this title, which concerns the  
35 labeling requirements for prescriptions for drugs, devices, or diagnostics;

1 (17) Violates any provision of § 12-603 of this title, which concerns the  
2 home dialysis distribution program;

3 (18) Advertises or otherwise publicly claims to dispense prescriptions or  
4 practice pharmacy in a superior manner;

5 (19) Advertises in a manner that tends to deceive or defraud the public;

6 (20) Is professionally, physically, or mentally incompetent;

7 (21) Is convicted of or pleads guilty or nolo contendere to a felony or to a  
8 crime involving moral turpitude, whether or not any appeal or other proceeding is  
9 pending to have the conviction or plea set aside;

10 (22) Is convicted of a violation of this title;

11 (23) Is disciplined by a licensing or disciplinary authority of any state or  
12 country or convicted or disciplined by a court of any state or country for an act that  
13 would be grounds for disciplinary action under the Board's disciplinary statutes;

14 (24) Violates any rule or regulation adopted by the Board;

15 (25) Refuses, withholds from, denies, or discriminates against an  
16 individual with regard to the provision of professional services for which the licensee  
17 is licensed and qualified to render because the individual is HIV positive;

18 (26) Violates any provision of § 12-507 of this title;

19 (27) Provides or causes to be provided confidential patient information to  
20 any person without first having obtained the patient's consent, as required by §  
21 12-403(b)(13) of this title and by Title 4, Subtitle 3 of the Health - General Article; or

22 (28) Fails to cooperate with a lawful investigation conducted by the Board  
23 or the Division of Drug Control.

24 12-403.

25 (b) Except as otherwise provided in this section, a pharmacy for which a  
26 pharmacy permit has been issued under this title:

27 (1) Shall be operated in compliance with the law and with the rules and  
28 regulations of the Board;

29 (2) Shall be located and equipped so that the pharmacy may be operated  
30 without endangering the public health or safety;

31 (3) Shall ensure that a licensed pharmacist be immediately available on  
32 the premises to provide pharmacy services at all times the pharmacy is in operation;

33 (4) Shall be supervised by a licensed pharmacist who is responsible for  
34 the operations of the pharmacy at all times the pharmacy is in operation;

1 (5) Shall provide complete pharmaceutical service by preparing and  
2 dispensing all prescriptions that reasonably may be expected of a pharmacist;

3 (6) Shall provide services to the general public and may not restrict or  
4 limit its services to any group of individuals unless granted a waiver from this  
5 requirement by the Board;

6 (7) May not offer pharmaceutical services under any term or condition  
7 that tends to interfere with or impair the free and complete exercise of professional  
8 pharmaceutical judgment or skill;

9 (8) May not make any agreement that denies a patient a free choice of  
10 pharmacist or pharmacy services;

11 (9) May not participate in any activity that is a ground for Board action  
12 against a licensed pharmacist under § 12-313 of this title;

13 (10) (i) Shall maintain at all times a current reference library that is  
14 appropriate to meet the needs of:

15 1. The practice specialty of that pharmacy; and

16 2. The consumers the pharmacy serves; and

17 (ii) Shall comply with any regulations adopted by the Board  
18 establishing the types of texts required to be included in the reference libraries in  
19 each of the various practice specialty pharmacies;

20 (11) (i) Shall maintain at all times the minimum professional and  
21 technical equipment and sanitary appliances that are necessary in a pharmacy:

22 1. To prepare and dispense prescriptions properly; and

23 2. To otherwise operate a pharmacy; and

24 (ii) Shall:

25 1. Be equipped with the minimum equipment and appliances  
26 specified by the Board under this section; and

27 2. Be kept in a clean and orderly manner;

28 (12) Shall store all prescription or nonprescription drugs or devices  
29 properly and safely subject to the rules and regulations adopted by the Board;

30 (13) Shall:

31 (i) Make and keep on file for at least 5 years a record of each  
32 prescription prepared or dispensed in the pharmacy;

1 (II) IMMEDIATELY AFTER DISCOVERING THE ERROR, REPORT TO  
2 THE CONSUMER, THE CONSUMER'S PRESCRIBING HEALTH CARE PROVIDER, AND THE  
3 BOARD ANY ERROR THE PHARMACY MAKES IN COMPOUNDING, DISPENSING, OR  
4 LABELING A PRESCRIPTION;

5 [(ii)] (III) Disclose the records and files maintained of prescriptions  
6 for drugs or devices that identify or may be readily associated with the identity of a  
7 patient only in accordance with the provisions of Title 4, Subtitle 3 of the Health -  
8 General Article; and

9 [(iii)] (IV) Keep additional records as required by the rules and  
10 regulations adopted by the Board;

11 (14) Except as otherwise provided under federal law, shall establish and  
12 maintain mechanisms to ensure that all prescription drugs or devices used within  
13 institutions that provide acute, subacute, or long-term care, or within their related  
14 corporate subsidiaries, but stored outside a pharmacy, are stored properly and safely,  
15 subject to rules and regulations adopted by the Board and policies established by the  
16 institution;

17 (15) Shall provide such personnel, automation, and technology as are  
18 necessary to allow the licensed pharmacist employee sufficient time to utilize the  
19 pharmacist's knowledge and training and to perform competently the functions of a  
20 licensed pharmacist as required by law;

21 (16) Shall provide such personnel, automation, and technology as are  
22 necessary to allow the licensed pharmacist employee to comply with the labeling  
23 requirements specified in § 12-505;

24 (17) With regard to a prescription drug that is delivered in this State by  
25 the United States mail, a common carrier, or a delivery service and is not personally  
26 hand delivered directly to a patient or to the agent of the patient at the residence of  
27 the patient or at another location designated by the patient, shall:

28 (i) Provide a general written notice in each shipment of a  
29 prescription drug that alerts a consumer that, under certain circumstances, a  
30 medication's effectiveness may be affected by exposure to extremes of heat, cold, or  
31 humidity; and

32 (ii) Provide a specific written notice in each shipment of a  
33 prescription drug that provides a consumer with a toll-free or local consumer access  
34 telephone number accessible during regular hours of operation, which is designed to  
35 respond to consumer questions pertaining to medications; and

36 (18) (i) May maintain a record log of any prescription that is requested  
37 to be filled or refilled by a patient in accordance with the provisions of Title 4, Subtitle  
38 3 of the Health - General Article;

39 (ii) If the prescription record of a patient includes the patient's  
40 Social Security number, shall keep the Social Security number confidential;

1                   (iii)     May not list in the record log the type of illness, disability, or  
2 condition that is the basis of any dispensing or distribution of a drug by a pharmacist;  
3 and

4                   (iv)     May not list a patient's Social Security number, illness,  
5 disability, or condition, or the name and type of drug received in the record log if the  
6 log is available to other pharmacy customers.

7     SECTION 2. AND BE IT FURTHER ENACTED, That the Board of Pharmacy  
8 shall adopt regulations to implement this Act on or before December 1, 2001.

9     SECTION 3. AND BE IT FURTHER ENACTED, That, on or before September  
10 30, 2002 and annually thereafter, the Board of Pharmacy shall report to the House  
11 Environmental Matters and House Economic Matters committees and the Senate  
12 Finance Committee on the impact of this Act and the regulations adopted under this  
13 Act on the frequency and severity in the State of pharmacy errors.

14     SECTION 4. AND BE IT FURTHER ENACTED, That this Act shall take effect  
15 July 1, 2001.